4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2335]

Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Statement of Work; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the Statement of Work to assess communication between FDA and sponsors through product quality information requests during application review and to identify best practices and areas of improvement. The independent assessment is part of FDA performance commitments under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). The independent assessment of FDA and sponsors in communicating through product quality information requests is described in detail in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027." As part of FDA performance commitments described in this document, the assessment will be conducted by an independent contractor. FDA is providing for public comment on the statement of work before revising as needed and requesting contractor proposals.

DATES: Either electronic or written comments on the statement of work must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT 30 DAYS AFTER

DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-2335 for "Prescription Drug User Fee Act VII Commitment to Assess Current Practices of the Food and Drug Administration and Sponsors in Communicating Through Product Quality Information Requests During Application Review." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Emily Ewing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1148, Silver Spring, MD 20993-0002, 240-402-0196, Emily.Ewing@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: PDUFA provides FDA with a source of stable, consistent funding that has made it possible for the Agency to focus on promoting innovative therapies and help bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a 5-year term. The program has been subsequently reauthorized every 5 years. To prepare for reauthorization of PDUFA for the next 5-year period (2023 to 2027), FDA conducted negotiations with the regulated industry and held regular consultations with public stakeholders, including patient advocates, consumer advocates, and healthcare professionals between September 2020 and February 2021.

Following these discussions, related public meetings, and Agency requests for public comment, FDA published the "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027" document, available at https://www.fda.gov/media/151712/download, also known as the PDUFA VII "goals letter," to supplement the statute. The goals letter includes the performance goals, procedures, and commitments that apply to aspects of the human drug review program that are important for facilitating timely access to safe, effective, and innovative new medicines for patients. Several of these commitments aim to continue to enhance communication between FDA and sponsors during application review.

FDA and sponsors interact in a variety of ways throughout application review. One such way is via a communication called an information request (IR), sent to an applicant as the discipline review occurs. FDA uses IRs to request further information or clarification that is

needed or would be helpful to allow completion of the discipline review. IRs may be in the form of letters, emails, or faxes.

FDA uses product quality IRs to request further information or clarification needed for FDA's assessment of identity, strength, quality, purity, or potency of drug substances or drug products. Ensuring that patients can have confidence in the safety and effectiveness of their medications is a longstanding priority for FDA. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have worked to address this priority in part by performing Chemistry, Manufacturing, and Controls (CMC) reviews for CDER-regulated and CBER-regulated products. CDER or CBER may issue a product quality, or CMC, IR as a result of CMC assessments conducted in support of the application.

IRs from both CDER and CBER are expected to follow Four-Part Harmony in which reviewers are expected to communicate: (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. This expectation can be found in CDER's Manual of Policies and Procedures (MAPP) 5016.8, "Communication Guidelines for Quality-Related Information Requests and Deficiencies." As a result of FDA's implementation of Four-Part Harmony in CMC-IRs, sponsors should understand what information FDA needs to continue their review. The PDUFA VII goals letter includes commitments for FDA to update and conduct training on existing policies and procedures (MAPPs and Standard Operating Policy and Procedure (SOPPs)), to reflect Four-Part Harmony. CDER MAPP 5016.8, "Communication Guidelines for Quality-Related Information Requests and Deficiencies" will be revised and made public. CBER SOPP 8401.1, "Issuance of and Review of Responses to Information Request Communications to Pending Applications" will also be revised.

In addition to updating the documents and conducting training, FDA is committed to contracting with an independent third party to assess current practices of CDER, CBER, and sponsors in communicating through product quality IRs during application review and effectiveness of Four-Part Harmony. This assessment will identify best practices and areas of

improvement in communications between FDA review staff and sponsors through product quality IRs and is the subject of this task order.

The Statement of Work can be accessed at: https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.

Dated: October 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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